BROOKSTEIN DECLARATION EXHIBIT 5

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.1	IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE IN AND FOR THE NEW CASTLE COUNTY
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3	DEPUY MITEK, INC., a Massachusetts) Corporation,)
•	Plaintiff,) Civil Action
· 4	v.) No. 04-12457 PBS ARTHREX, INC., a Delaware)
5	Corporation.
.6	Defendant.) HIGHLY CONFIDENTIAL
7	CONFIDENTIAL - NON-PATENT ATTORNEY'S EYES ONLY
8	
9	deposition of:
10	BRIAN HALLETT
10	taken at:
11	The Castle Hotel Castle Green
12	Taunton
13	Somerset - UNITED-KINGDOM
14	on 11th Januar 2006
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46 MR. BONELLA: What do you mean by that?

MR. TAMBURO: -- but I take you at your

3 word that this is the 30(b)(6) portion of

- the deposition, and again, to the extent that
- this testimony you are requesting right now is
- duplicative of testimony that was already given
- by Pearsalls in the past for this topic, topics 7
- number 4, 5, 6 and 7 of the original notice,
- Arthrex and Pearsalls are objecting to the
- 10 duplicative testimony requested.

11 MR. BONELLA: Let's just move on. We will I undergo the stretching in all processes before that?

- resolve it later. Exhibit 280. Do you 12
- recognize that, Mr. Hallett? 13
- A I recognize it as it is. 14
- 15 . What is Exhibit 280?
- A It is a result of a batch of US2 16
- 17 FiberWire.
- O Exhibit 280 is batch testing results? 18
- A Hmm hmm. 19
- 20 Q The tests describe in Exhibit 280 are,
- 21 those tests that are run in the standard, ordinary 22 business of Pearsalls?
- A Correct. 23
- Q Do you see the test at the intermediate 24
- 25 stage?

- 1 that have undergone the dyeing and scouring 2 processes and all processes before that?
 - A Yes.
- Q You have labeled Exhibit 280, "Stretch 5 stage"?
- A Hmm hmm.
- Q On Exhibit 279; correct? 7.
- A Yes.
- Q The samples -- I am sorry, the stretch 10 stage testing that is in Exhibit 280, does that
- A Yes. 12
- 13 Q The samples that have gone -- that are
- 14 stretch-tested in Exhibit 280 -- I am sorry, I will
- 15 rephrase the question. The samples that have been
- 16 stretch-tested as reflected in Exhibit 280 have not
- 17 been coated. Is that correct?
- 18 A. No.
- "No", it is not correct? 19 0
- 20 A No. It is not correct.
- Q The samples that have been stretch test --
- 22 I am sorry, the samples that are tested at the
- 23 stretch stage have undergone the stretching and
- 24 coating processes?
- 25 A Yes.

- Can you label in the manufacturing
- 3 flowchart where that test was done? Can you label
- 4 that as the intermediate stage? Okay. So, where you
- 5 have labeled Exhibit 280 interim/stage on Exhibit
- 6 279 reflects the intermediate stage testing done in 7 Exhibit 280?
- A Yes.
- Q If you could identify -- there is
- 10 a measure stage testing in Exhibit 280; correct?
- A Hmm hmm.
- O Could you label on Exhibit 279 where the 12 13 measure stage testing is?
- A So, do you want me to put the --
- O If you could just put, "Measure stage"? 16 "Exhibit 280 measure stage", and there is also the
- 17 stretch stage. Would you label where that is in
- 18 Exhibit 279? And there is also the dye stage
- 19 testing. Could you label where that is in Exhibit
- 20279? Exhibit -- you have labeled in Exhibit 279,
- 21 "Exhibit 280 dye stage", and that refers to the dye 22 stage testing in Exhibit 280?
- Yes. Α 23
- Q The dye testing that is done in Exhibit 24 25 280, is that all -- is that of samples of FiberWire

- Are you sure about that?
- Repeat the question again. 2
- Sure. The stretch testing, samples that
- 4 are tested at the stretch stage as in Exhibit 280,
- 5 have they undergone the stretching and coating 6 processes that are reflected in Exhibit 279?
- MR. TAMBURO: Asked and answered, 8 objection.
- 9 MR. BONELLA: Mr. Tamburo is going to
- 10 object to questions, but unless he instructs
- you not to answer you have to answer the 11
- question. 12
- A Yes. 13
- 14 O The intermediate stage testing, have those
- 15 samples been stretched and coated?
- A Yes. 16
- O What is the difference between the 17
- 18 intermediate stage testing and the stretched stage
- 19 testing samples?
- A They are tested before they are actually 20 21 coated.
- 22 Q Which are tested before they are coated?
- 23 A The yarn. The braid.
- O The samples that are tested during the 24
- 25 stretched stage, have they been stretched?

1 process? 1 FiberWire undergoes this stretching process here; 2 right? A It is not a stretch as such, it is just --3 we call it stretching because it is run through some 3 A Correct. O Now, when the yarn comes in and goes 4 pads just to align all of the filaments in the yarn. Q What do you mean by that? 5 through the stretching process, does any material 6 change take place during the stretching process? A Well, it just pulls it straight. O Pulls it straight? The material isn't MR. TAMBURO: Same objection. 8 A No. 8 stretched? 9 MR. BONELLA: Are there any changes in the A Very minute. strength characteristics of the yarn after O Very minute. And then the coating that we 10 11 see here, it goes through a bath or a dip of glue 11 the --12 seal and then the FiberWire is put through? 12 A Yes. O Let me rephrase the question. During the A It is a bath. We use it as a bath. 13 14 stretching process, is there any change to the O "Bath". Okay. And what is the rate at 15 which the yarn passes through the bath? 15 stretch properties? MR. TAMBURO: Same objection. A 20 metres per minute. 16 Q Is that the same for all FiberWire? 17 A Yes. 17 18 MR. BONELLA: In what way? A Yes. 18 O And then this machine here dries it? 19 A It gets stronger. 19 Q The yarn is stronger after the stretching A There are four (inaudible) which actually 20 20 21 dry it as it is going through. 21 process? O And then it is wound up to a bobbin at the 22 A Yes. 23 Q When you say, "Stronger", what type of 23 other end? To that bobbin on the other end. 24 strength are you talking about? 24 $\cdot \mathbf{A}$ Now, as the FiberWire yarn itself goes A The long strength of it goes up. 25 25 O The long strength of it goes up? 1 through the stretching and then the coating, does 2 the process change in anything itself? MR. TAMBURO: Object to the form of the 3 Q How about the tensile strength? question, calls for a legal conclusion. Q Any other strengths that go up or down A Do I have to answer that? 5 6 before or after the stretching process? MR. TAMBURO: You can answer, yes. 6 MR. TAMBURO: Objection, outside the scope A It actually makes it stronger in the of this 30(b)(6) notice. The questions were 8 lubrication of the actual suture when it is being asked and answered already previously in the 9 used afterwards. 10 United States during the previous 30(b)(6) MR. BONELLA: The material that is 10 braided, the yarn, both the PET and the deposition, so I object to this line of 11 11 polyester, does any material change happen to 12 questioning. 12 A The extension goes down. 13 them? 13 MR. TAMBURO: Object to the form of that 14 MR. BONELLA: The what does? 14 15 A The extension. question. 15 O What do you mean by extension? 16 MR. BONELLA: So, no material change 16 happens to the polyester and ultra high A It doesn't need so much -- more stretching 17 17 molecular weight polythethylene as the 18 in the braid. 18 FiberWire goes through the stretching and 19 Q No more stretching in the braid. Is that 19 20 something that happens after? coating processes? 20 Yes: 21 MR. TAMBURO: Same objection. 21 22 What does that alter in the property? 22 A No. 23 A Extension. MR. BONELLA: To the wire? 23

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A Can you repeat the question?

Sure. The FiberWire yarn for all sizes of

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A Yes.

Q Is that the same as elongation?

86

1	Q	Does the modulus for the material change
2	during	the stretching process?

- 3 MR. TAMBURO: Same objection.
- 4 I don't know.
- 5 MR. BONELLA: Is there testing done on
- 6 that?
- 7 A No.
- 8 Q Do you know what I mean by, "Modulus"?
- A Whether it alters.
- 10 O Right.
- 11 Α Yes.
- 12 Q Do you know what the modulus is referring
- 13 to?
- A I should imagine the make-up of the ultra 14 15 high ...
- O The modulus I am referring to would be the 17 slope of the stress strength, the stressed strain 18 curve.
- 19 A The curve of the --
- 20 No. If you did a test, a stress strain-
- 21 plot for FiberWire before and after the stretching 22 process, does the slope of that curve change at all 23 with respect to the FiberWire?
- MR. TAMBURO: Objection, calls for 24
- 25 speculation, asked and answered.

- A It helps to penetrate the new seal coating 2 within the braid structure. It dilutes the coating 3 as well as attaching itself.
- Q Where in the processing is the Xylene 5 added to the machine?
- A In the tank.
- Q So, is the Zylene mixed together in the 8 tank for the FiberWire to be put through it?
- A That's correct.
- 10 Q Any material properties change to the 11 FibreWire yarn itself during the stretching and the 12 coating process?
- 13 MR. TAMBURO: Object to the form of the 14 question. Calls for an expert conclusion, and 15 outside of the scope of this 30(b)(6) notice.
- 16 A Change?

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- MR. BONELLA: Any material process altered by the ultra high molecular weight polythethylene or the polyester?
- MR. TAMBURO: Object to the form of the question, calls for a legal conclusion and speculation and it has already been covered in
- 23 a previous 30(b)(6) deposition.
 - A I don't know.
- 25 Q You don't know?

I don't know. 1

- MR. BONELLA: You don't know whether it
- 3 does?
- A Correct.
- O Now, in the dyeing process, what pressure 6 is that done at? I am sorry, the coating process.
- 7 The coating process. What temperature is that done
- 8 at?
- I am not. 27 degrees.
- 10 Q Celsius?
- Yes.
- Q Pressure? What is the pressure? 12
- 13 Atmospheric?
- A I don't know. 14
- There is no pressure put into this 15
- 16 machine?
- A No. 17
- 18 Q Is there a solvent used in this coating?
- 19 A Yes.
- What is that? 20 0
- 21 Xylene (Phonetic). Α
- 22 Q Any other material used in the coating 23 process?
- A No. 24
- 25 Q What is the purpose of the Xylene?

- 1
- 2 Q Why don't you know?
- 3 A I am not sure of the question you are 4 asking.
- Q For example, the ultra high -- the
- 6 FiberWire braid that goes, that comes out of the
- 7 stretch, then goes through the process, after it has 8 been coated, does anything change with respect to
- 9 the FiberWire ultra high molecular weight
- 10 polythethylene, or does anything change with respect 11 to the polyester?
- 12 MR. TAMBURO: Object to the form of the
- question. If you want to narrow it down, it has 13
- 14 big properties, but that is a very broad
- 15 question, the way it has been worded.
- A The only thing I can say is that the
- 17 changes are not altered. That is the whole idea of
- 18 putting the coating on, and I hope it makes it more 19 easier for when the surgeon actually ties the knot.
- 20 Q Is there anything else that changes?
- 21 A Not that I am aware of.
- 22 Q Okay. Now, does the tensile strength
- 23 change before or after the coating?
- 24 MR. TAMBURO: Objection. Same objections
- 25 a previously noted.

23 (Pages 86 to 89)

1 number 2 bobbin was before the coating, the 2 stretching, and the bobbin after the coating 3 stretching, is that --

A It does help.

Q. It does help? Is there any other -- is 6 there any carrier bobbins during this process?

O There is only two bobbins, the beginning 9 and the end?

14 pad.

What part of the yarn is stretched? 11

A There is no stretch. I have told you 13 that. The only stretch taking place is through the

Q Through the pad? 15

A And it is very minute. It is taking off 17 the excess coating, and aligning all the film within 18 that braid.

Q Is the speed at which the bobbin in moves 20 itself the same as the output bobbin?

A Or -- it doesn't matter. I think it

22 doesn't matter. They are bound to vary because that 23 one is taking on more than that one over there.

Q The stretching process that you are 25 referring to is the pads, are you saying that it

question, and it calls for expert testimony. 1

2 A I don't know.

3 . MR. BONELLA: You don't know? Right. Do you know the specification parameters for what 4

tension that the varn is under during the 6 stretching process?

7 MR. TAMBURO: Object to the form of the 8 question. That testimony -- mischaracterizing 9 the prior testimony.

10 MR. BONELLA: I am sorry. Is the

FiberWire under tension during the stretching 11

12 process?

A Yes. 13

14 Q Where is the specification for that?

A It is written down in the process. 15

Q In the process. Okay. We need to go off 16 17 the record.

18 (11.48 am)

OFF THE RECORD

20(11.53 am)

MR. BONELLA: Mr. Hallett, when you 21 22 referred to a pad, do you mean a rubber roller?

23 Rubber pads.

Rubber pads. Not a roller? 24 Q

25 Α

1 goes to a line yarn?

A It takes off any excess coating.

Q After that? 3

Yes.

O Now, the oven process that we have here, 6 I think you referred to it as drying and the curing?

A That's correct.

Q Is the drying process here a technical 9 curing process, or is it just drying the yarn?

MR. TAMBURO: Object to the form of the

question. 11

A It does. 12

MR. BONELLA: What do you mean by that? 13

A Well, it is actually acting as a -- it 15 dries out the coating, it burns off any excess 16 chemicals as it comes through the bath, and it acts 17 as actually purifies the new coating.

Q Purifies it? What do you mean by that? 18

A Without speculation, I would just imagine 20 it is - fills in any gaps and makes sure it is

21 completely covered.

O Is there material change that takes place 23 during the -- is there any change that takes place 24 on the coating during the drying process?

MR. TAMBURO: Objection to the form of the 25

Can you describe the pads? 1

2 I can show you one, if you want.

Q Can you show me one? These are the rubber 3 4 pads? (Pause)

These are rubber pads. This is 6 a white one and a brown one?

A Yes.

8 Can you describe how they work?

A The braid is sandwiched in between, so

10 these are put in between two brackets. The brackets 11 are screwed down as tight as possible allowing just

12 the minimum of braid to come through. So,

13 therefore, that does allow a little bit of stretch

14 and it takes off the excess Nusil. So, what we have 15 is a brown pad and a white pad and the FiberWire. 16 goes between the two.

Q The two pads remove excess coatings? 17

That's correct. 18

19 They subtely stretch the yarn?

A Under some tension, yes. 20

O Do you know what that tension is? 21

A Yes. 22

23 Q Is it measurable?

MR. TAMBURO: Object to the form.

A No.

25 (Pages 94 to 97)

118 Yes. testing have they all undergone two cycles of It was just the --2 the coating? That is done for the machine when it is 3 A They would have done, yes. MR. BONELLA: If we could move to the 4 set up for -- before they go in with a full run, to 5 make sure the parameters are set up correctly within final stage that would be great. 6 (12.40 pm) 6 the machine. O It would be fair to say that -- wouldn't OFF THE RECORD 8 you have the input bobbin material, it goes through 8 (12.42 pm) 9 the stretching, coating, drying process, comes up or MR. BONELLA: Are we in the room where the 10 the take-up roller and a portion of that is sampled 10 time inspection and measuring process is 11 from over here, tested, and you can figure out what 11 performed? A That's correct, yes. 12 the knot pull, straight pull are, and if they are 12 13 acceptable, then continue on with the process? 13 What is the time inspection and measuring A That's correct. 14 process performed in this room? Then the intermediate sample is taken at A It is wound to a final bobbin which is 15 · · Q 16 actually then sent out to the customer. 16 some point? A That is done afterwards. Q Any tensioning that is applied to the yarn 17 17 18 during this process? 18 Q After the whole process is completed? A Only through a clock which is actually 19 Α Yes. "Come over here, test the..." 20 giving the length, and the tension is given by the 20 Q. A percentage of that batch is tested. 21 girls who actually control the speed of the bobbin 21 22 which is taken off. Is tested, and that is the representative 22 23 of the batch? 23 Q It is minimal tension? 24 Very minimal. A 24 Yes. 25 Then we have the measure stage testing? Q Okay, and what is performed during this 119 1 process? After we do the measure stage, "Come up A They are looking for any defects within 3 the braid, and they are giving it a measured length. 3 here, do the tests again"? Q A measured length on a spool? A Yes. 5 Yes. Couple more questions. After the Α 6 FiberWire runs through the coating, stretching What is the standard length? It depends on the size. On US2 I believe 7 process, is there a way to measure the amount of 8 it is 500 metres. 8 coating that is on the FiberWire? 9 Q And for US5? A No. Pearsalls typically doesn't do that. 10 A It is 250. 11 Okay. When the -- each FiberWire goes through tw d i Q For the other sizes? 12 of the coating stretching processes? 12 A thousand, 500, it depends on which size. 13 For Size 0? 0 13 That's correct. Q Is there a way to tell how much coating is 14 That is a thousand metres. A 14 00 would probably be 2000. The 000 would 15 applied in the second process versus the first 15 16 be 3000. And 4000? 16 process? 10000. 17 17 A No. 0000 is 3000? Q Is it less than the first process? 18 Q 18 19 Α 3000. 19 Generally? Q Okay, and after it undergoes this process 20 I don't think so. You don't think so? Well, I don't know. 21 then it goes back to the measuring in the QA in 21 22 which measuring and testing is performed? MR. TAMBURO: Objection, calls for 22 A It is labeled as well here. 23

31 (Pages 118 to 121)

Q It is labeled here? Okay. All right.

25 Good. Thank you for your hospitality and showing us

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MR. BONELLA: For the samples that are

tested in the stretch and intermediate stage

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	227
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1 affect the testing results, the knot strength	1 Q Have all the products listed in Exhibit
2 testing results?	2 318 been sold for commercial use?
3 A Not generally it doesn't.	3 A I don't know.
4 Q How about the testing? Can the testing	4 Q How was this chart prepared?
5 show variations in the testing results?	5 A It was prepared by myself and one of the
6 A Sometimes, yes.	6 engineers at Arthrex.
7 Q But you don't know for sure why the	7 Q Who? What Arthrex engineer?
8 specifications changed?	8 A Tara Shanoville (Phonetic).
9 MR. TAMBURO: Objection. Asked and	9 Q Why were how did you select certain
10 answered.	10 products for entry into this matrix?
11 A No.	11 A Most of them would have been what they had
MR. BONELLA: In Exhibit 316, do you see	1.
13 the second column under number 5 FiberWire	13 Q What Arthrex had been ordering?
14 lists a green product?	14 A Yes.
15 A Yes.	15 Q What about what Arthrex didn't order?
16 Q Similarly, Exhibit 317, the second column	16 A Similarly they were listed.
17 lists a green number 5 FiberWire. Do you see that?	
18 A Yes.	18 A Because it may happen at some time or not.
19 Q Has Pearsalls manufactured green number 5	
20 FiberWire for commercial use?	20 first product, PS 30, has that been manufactured for
21 A No.	21 commercial use?
Q The products shown on Exhibit 316, have	22 A Yes.
23 they all been manufactured for commercial use other	
24 than the green FiberWire, number 5? 25 A Yes.	24 that been manufactured for commercial use?
25 A Yes.	25 A Yes.
245	0.47
245	247
1 Q How about Exhibit 317? Other than the	1 Q How about PS 12/2? Has that been
1 Q How about Exhibit 317? Other than the 2 green number 5 FiberWire, have all those other	1 Q How about PS 12/2? Has that been 2 manufactured for commercial use?
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304 306 Q No you don't know? 1 samples 100% -- you see later down in the letter it 2 I don't know. Α 2 savs: Q If you turn back to PR 8008, the 185/16 3 "Can you build a 25% Dyneema/75% 4 product with the definition of braid that we have 4 polyester blend in a size 2 that is very flexible 5 been talking about being a braid of two different 5 (like the existing suture or the ethicon sample) and 6 materials braided together, with that definition, 6 send it to me to test". 7 does the 185/16 have a braid of two different Do you see that? 8 materials braided together? 8 A Yes. A No. 9 Q In the top paragraph does the sample of 10 O 185/16 is two different materials because 10 the Dyneema material, does that refer to a braid of 11 it has one material in the core and one material in 11 100% Dyneema? 12 the cover? 12 A I can't remember. 13 A Yes. 13 Q Do you recall ever making a construction 14 Mr. Hallett, I will show you DePuy Mitek 14 that was 100% ultra high molecular weight 15 Exhibit 323. It is PR 7507 through 7512. Do you 15 polyethylene for Arthrex? 16 see the Dyneema property sheet that is attached to 16 A I can't remember. 17 the document? O In November '98 is that when FiberWire was 17 18 (DePuy Mitek Exhibit 323 marked for identification) 18 first being developed? 19 19 A Yes. Q Have you ever seen that before? 7508 20 What did you understand Mr. Grafton to 20 21 through 7512? 21 mean when he said: 22 Yes. Α 22 "Can you build a 25% Dyneema/75% 23 Q Yes? 23 polyester blend in Size 2 that is very flexible". 24 A Yes. 24 What did you understand that to mean? 25 Q Is that the market literature from Dyneema 25 A Yes, that he wanted a braid which was 305 307 1 with respect -- I am sorry. Is 7508 through 7512 1 more -- not so stiff. 2 marking literature from DSM on its Dyneema product? Q As the 100% ultra high molecular weight A That's correct. 3 polyethylene? O Does this describe the Dyneema that was A Yes. 5 used in FiberWire? Q He wanted Pearsalls to try to put A Yes. 6 polyester with --O In the back it refers to the datasheet for A With the mixture. 8 SK65. Q With a braid. He wanted -- let me finish A Hmm hmm, 9 the question before you answer. 10 Q Was that SK65 ever used for FiberWire? Mr. Grafton wanted Pearsalls to braid A Yes. 11 11 polyester with the ultra high molecular weight 12 Q It was? 12 polyethylene so that the polyester could provide 13 A Sorry. I think it was SK64. 13 flexibility? 14 O That was used? 14 A Yes. 15 A Yes, because the finer sizes, I don't Q Next I will show you Exhibit 325. It is 16 think they did it in an SK65. 16 Bates number PR 6493. Do you recognize Exhibit 325 Q Mr. Hallett, I am going to show you DePuy 17 as a letter from you to Mr. Grafton from November 18 Mitek Exhibit 324. It is PR 6556. Is Exhibit 324 18 1998? 19 a letter that you received from Mr. Grafton on about 19 (DePuy Mitek Exhibit 325 marked for identification)

21 (Pages 304 to 307)

20

21

22

A Yes.

O And the letter said:

"Please find enclosed a matrix of

23 information of the samples that you took with you on

24 your visit to Pearsalls, I will endeavour to proceed

25 with the existing trial to match US2 Excel Braid

20 November 16th, 1998?

A Yes.

23

21 (DePuy Mitek Exhibit 324 marked for identification)

Q It says in the letter to you that,

24 "We...", referring to Arthrex, "... had tested the

25 samples of the Dyneema material". Were those

308 310 1 made by Ethicon, in Polyester construction. The next A Later part of last year. He still works 2 Poly/Dyneema samples should be with you by the end 2 at -- in Pearsalls. 3 of the week". Q What do you mean by that? Do you see that? A He has been re-employed by a company A Yes. 5 called, "Novasive". Q Then you list four samples and the yarn Q Is that a company that is related to 7 type, and the first one is Dyneema and the next 7 Pearsalls? 8 three are poly/Dyneema? A No. A Yes. 9 Q So, Mr. McLeod is not employed by 10 Q Was the first sample 100% Dyneema? 10 Pearsalls? 11 A Yes. 11 A No. Q The second through fourth samples were 12 12 Q No he's not employed? 13 a blend of, or a braid of polyester and Dyneema? 13 A He's not employed by Pearsalls. 14 A Correct. 14 Q But he was? Q The 100% Dyneema had higher -- did they 15 A He was. 16 all have the same size? Do you know if these were 16 Q Do you see in his letter he says the first 17 all the same size, number 2, or --17 lot of PA 26 was produced as a development sample, A I can't remember. 18 DTPA 26? 19 Q When Pearsalls was developing the 19 A Hmm hmm. 20 FiberWire, was it trying to -- was it comparing it 20 Then he goes on to say, in the second 21 against the Ethicon XL product? 21 paragraph, or the third paragraph, that: A I believe it was -- I don't know 22 "Future orders will be supplied 23 whether -- what it was comparing this to, but I was 23 against the specification PA26B". 24 asked to make a braid compared with US5, a US5 24 Do you see what? 25 diameter. 25 A Yes. 309 311 Q Yes, but do you see the reference to Q In April 2001, is that when the -- it was 2 trying to match the US 2 XL braid made by Ethicon? 2 decided to use the PA 6B code for number 2 3 Do you see that? 3 FiberWire? A Yes. 4 A It was decided, sorry? Q My question is; just generally in the Q It was decided to use the PA 6B code for 6 development of FiberWire was Pearsalls comparing the 6 number 2 FiberWire? 7 products it was developing for FiberWire to A Yes. 8 Ethicon's XL products? Q If you turn to page ARM2146, do you have A Yes. 9 that page? ARM2146? Do you see it says: 10 Q Was Pearsalls comparing the FiberWire "The specification of the polyester 11 products that it was developing to any other 11 is Type 712 and it is manufactured by KoSa GmbH & 12 products during its development? 12 Company KG". 13 A Not that I can remember. 13 A Yes. Q Next I will show you DePuy Mitek Q Is the polyester that Pearsalls has used 15 Exhibit 326. It is ARM2141 through 2147. First of 15 for FiberWire always been manufactured by KoSa GmbH 16 all, I will see if you have any objections to the 16 & Company KG? 17 Arthrex Bates numbered document? 17 A Yes. 18 (DePuy Mitek Exhibit 326 marked for identification) 18 Q Mr. Hallett, I will show you DePuy Mitek 19 MR. TAMBURO: No objection. 19 Exhibit 327, case number ARM2351, if you have no 20 20 objections, Sal? MR. BONELLA: Mr. Hallett, is Mr. McLeod 21 someone who works with you? 21 (DePuy Mitek Exhibit 327 marked for identification) 22 A He did work for us. 22 MR. TAMBURO: No objections. 23 Q He has left Pearsalls? 23 MR. BONELLA: It says: 24 A Yes. 24 "The first shipment of 61,000 metres of

22 (Pages 308 to 311)

O When did he leave Pearsalls?

25

25

new Blue FiberWire 2 is leaving today to RK".

MR. TAMBURO: Object to the form, and seeking expert testimony.

3 A I don't know.

MR. BONELLA: You don't know?

A No.

Q What type of variation would you see to 7 make you think it was a big increase or a big 8 decrease between the dye stage and the measure 9 stage?

MR. TAMBURO: Object to form.

A It could be up to about a kilo. 11

MR. BONELLA: How much? 12

13 A One kilo.

One kilo? 14

A Yes. 15

O It could be more than that?

A Hmm hmm. 17

Q Could it be up to two to three kilos? 18

A I wouldn't think so, no. 19

Q You wouldn't think so. I will show you 20

21 Exhibit 339. It is Bates numbers PR 3730 through

22 3734 and it is entitled, "Pearsalls Sutures Results 23 for Batch 26866". Mr. Hallett, do you recognize

24 Exhibit 339 as a Pearsalls sutures Batch Record for

25 batch 26866?

A Yes.

2 stage it went up by over 1 kilo?

Q And then at the measure stage it went down 5 over 1 kilo from the intermediate stage?

1 there between the dye stage and the intermediate

A Yes.

Q But the difference between the dye stage 8 and the measure stage was 0.11 kilos?

A Yes.

10 Q Do you know what might account for the 11 difference between the intermediate stage and the 12 measure stage?

13 MR. TAMBURO: Object to the form.

14

15 MR. BONELLA: Do you know why the dye 16 stage and the measure stage were about the same

but the intermediate stage was about a kilo 17

18 greater, over a kilo greater?

19 MR. TAMBURO: Object to form.

20 A No.

21 MR. BONELLA: Is that a concern, that

22 level of variation?

23 MR. TAMBURO: Object to form.

24 A No.

25

7

MR. BONELLA: Why?

1 (DePuy Mitek Exhibit 339 marked for identification)

A Yes.

3 MR. TAMBURO: You don't have another copy

4 of that?

MR. BONELLA: No. I couldn't truck over 5

three copies of all of these. If you look at

the Pearsalls sutures Works Order for Exhibit

399 it refers to the product code of 37G500500.

A Yes.

Q That is the product code for number 2 blue 10

11 FiberWire?

12

A Yes.

O Exhibit 339 is a record for batch 26866

14 for number 2 blue FiberWire?

15 A. Yes.

Q If you look at the dye stage testing, the 17 average knot strength, knot pull was 15.64?

A Hmm hmm. 18

Q Then if you look at the intermediate stage 19 20 testing, it was 163990?

A Yes.

Q Then if you look at the measure stage

23 testing, it was 15.03?

A Yes. 24

Q Do you know what account -- do you see

A Because I think you will see it reaches 2 the requirements of that specific size.

Q You don't know what would cause it to go 4 down between the intermediate stage testing and the 5 measure stage testing?

343

MR. TAMBURO: Objection. Asked and

answered.

8 A It could be the operator.

MR. BONELLA: Just the operator?

10 A Yes.

11 Q It could be how they tie the knot?

12 A Yes.

Q I will show you Exhibit 340. It is PR

14 4308 through PR 4321. It is Pearsalls sutures

15 results for batch 25330. Do you recognize Exhibit

16340 as the Batch Record for batch 5330?

17 (DePuy Mitek Exhibit 340 marked for identification)

18 A Yes.

19 MR. TAMBURO: Have you got another copy of

20

21 MR. BONELLA: No. If you go to the back

22 you will see the product code is 25330?

23 A Correct.

Q Exhibit 340 is the batch record for number 24

252 FiberWire blue, batch 25330?

344	
1 A Yes.	1 MR. TAMBURO: Object to form and seeking
2 Q If you look at this document you will see	2 expert testimony. Do you have a copy for
3 that the dye average the average knot strength at	3 counsel, Mr. Bonella?
4 the dye stage was 16.26; right?	4 MR. BONELLA: I have one copy of the Batch
5 A That's correct.	5 Records. I didn't even bring one for me.
6 Q And then at the intermediate stage, the	6 A That is the operator testing.
7 average knot pull strength was 16.53, right?	7 Q Operator testing?
8 A Correct.	8 A Hmm hmm.
9 Q And then at the measure stage, the average	9 Q Do you know what would account for the
10 knot strength was 16.75?	10 increase in average knot pull strength between the
11 A That's correct.	11 intermediate stage and the measure stage?
12 Q So, between the dye stage and the	12 MR. TAMBURO: Same objection.
13 intermediate stage, the difference in the knot pull,	13 A Yes.
14 average knot pull was less than 0.3 kilos?	14 Q What is that?
15 MR. TAMBURO: Object to form.	15 A Because it has been coated.
16 A Correct.	16 Q Coated?
17 MR. BONELLA: And the difference between	
18 the average knot strength between the	18 Q If it increases when it is coated, we saw
19 intermediate stage and the measure stage was	19 other ones where it decreased when it was coated?
less than 0.3 kilos as well; right?	20 A Very slightly.
21 A That's correct.	21 Q In Exhibit 339, the average knot pull
22 Q Are these numbers, this 16.26, 16.53,	22 decreased between intermediate and measure from 16.9
23 16.75, are they considered to be all about the same,	
24 based on the tolerances?	24 A Yes.
25 A That's right.	25 Q Do you know why that would be?
345	347
1 Q Next I will show you Exhibit 341. It is	1 A No. Operator.
2 PR 3778 through 3791 entitled, "Pearsalls Sutures	2 Q What accounts for the so, with Exhibit
3 Results for Batch 5899", do you recognize Exhibit	3 341 you are saying the decrease between the dye ar
4 341 as the Batch Record results for batch 5899?	4 the intermediate stage was due to coating?
5 (DePuy Mitek Exhibit 341 marked for identification) 5 MR. TAMBURO: Objection. Asked and
6 A Yes.	6 answered.
7 O Would you turn to the Work Order on PR	7 A The increase.
8 3791? Do you see the product code is 35G500?	8 MR. BONELLA: I am sorry, the increase,
9 A Correct.	9 but didn't it go from it was 15 in
0 Q Batch 25891 is for number 2 blue	10 Exhibit 341, the average knot pull in dye was
1 FiberWire?	11 15.361, right?
2 A Yes.	12 A Yes.
· · · · · · · · · · · · · · · · · · ·	
3 Q If you look at the testing you will see	
4 that the average knot pull strength at the dye stage	•
5 was 15.61, correct?	15 Q And the average knot pull at the
6 A That's correct.	16 intermediate stage was 14.483, right, and that is
7 Q The average knot pull strength at	17 after coating?
8 intermediate testing was 14.83?	18 A Hmm hmm.
9 A That's correct.	19 Q What caused the knot pull to go down from
O Q The average knot strength at the measure	20 the dye stage to the intermediate stage?
1 stage was 16.87?	21 MR. TAMBURO: Objection, calls for exper
2 A That's correct.	22 testimony, asked and answered. Calls for
3 Q Do you know what would account for the	23 speculation.
4 decrease in average knot pull strength between the	24 A I don't know.
25 decrease in average knot pun suchgui between the	25 MD DONELLA: Von don't know?

31 (Pages 344 to 347)

MR. BONELLA: You don't know?

25 dye stage and the intermediate stage?

· A No. MR. TAMBURO: I think he knows only what Q How do you know at the measure stage it 2 I know. He wasn't there watching it when it 3 was -- in Exhibit 341 it was 16.482; right? 3 was done. A So it is increased. MR. BONELLA: All right. I will take your 4 Q Check numbers. But how do you know -- it 5 representation that it is what it is. 6 is increased. There is nothing done with the suture 6 I will show you DePuy Mitek Exhibit 343. 7 between the intermediate stage and the measure stage 7 It is a three-page document test recorded 8 that would change the property of the suture; right? 8 summary and sign-off sheet from Arthrex. Sal. A Hmm hmm. 9 do you have any problems in me showing him 10 Q Right? 10 Exhibit 343? It was disclosed to J&J as A Yes. 11 11 non-contentious. 12 Q Yes, I am correct? 12 MR. TAMBURO: No objection. 13 A Yes, you are correct. 13 MR. BONELLA: Mr. Hallett, I am showing Q How do you know which one's right, the 14 you Exhibit 343. I believe it has Brian 15 decreased one at the intermediate stage or the 15 Hallett's writing on the first page, I believe 16 increased one at the end stage? it is a document from Arthrex. Have you ever 16 17 MR. TAMBURO: Calls for expert testimony 17 seen this document before? 18 and object to the form. 18 (DePuy Mitek Exhibit 343 marked for identification) 19 MR. BONELLA: Or were they all about the 19 A Yes. 20 same? 20 Q You have? 21 A They all vary. 21 Α Hmm hmm. O Well, if you look at the testing you 22 22 Q When did you see it? 23 cannot really say - are they all within the 23 A Sometime last year. 24 tolerance of the testing so that you cannot really 24 Q And why did you see it? 25 say that one of these values is greater than the 25 A I think it was describing or showing the 349 351 1 other? 1 test procedure for doing a braid load on the loops. 2 MR. TAMBURO: Objection, calls for exper Q On what? 3 testimony and speculation. 3 On the loop. 4 A Yes. Q If you look at the top it says the 5 MR. BONELLA: That's correct? 5 description of the procedure on the first page is 6 number 2 FiberWire 2174 coated and uncoated USIPG 6 A Yes. MR. TAMBURO: Mike, this is the 7 7 dyed, and the date is February 16, '04, and the type 8 once-passed coating sample of US2 FiberWire. 8 of test it says, knot tiedown, and it says: We don't have a Bates number but I will send "The test objective: To determine 9 10 you a Bates number by e-mail. It is a little 10 the peak force required to advance a single half capsule labeled, "Sample Pearsalls Limited blue 11 11 hitch using coated and uncoated Fiberwire suture". 12 FiberWire single coating 15 metres US2 batch. 12 Do you see that? 13 number 28790". 13 A Hmm hmm. 14 MR. BONELLA: Okay. We will mark it as 14 The test method is described as: DP342 and ask Mr. Hallett if you can identify 15 "The 50lb load cell was attached to 16 DePuy Mitek Exhibit 342, or take counsel's 16 the MTS Sintech 1/S and calibrated. A custom representation that it is number 2 blue 17 17 fixture as shown was used to simulate knot tying FiberWire that has been run through the 18 that would occur clinically. The top end of the 18 19 coating, stretching and drying process only one 19 suture was clamped in a custom fixture that was time. Is that correct? 20 attached to the load cell, and then a single half 21 (DePuy Mitek Exhibit 342 marked for identification 21 hitch was tied around a guide block such that the 22 MR. TAMBURO: That is my understanding 22 loop length was consistent between samples. 23 23 A weight of .375 kg was then attached to the free 24 MR. BONELLA: Can he testify to that? 24 end of the suture in order to tension the loop. 25 Does he know? 25 Care was taken to tension the legs of the suture

32 (Pages 348 to 351)

BROOKSTEIN DECLARATION EXHIBIT 6

11/16/1998 10:24

941-543-6218

ARTHREX SCHMIEDING

PAGE 61



November 16, 1998

Brian Hallert
Pearsalls Strongs
Tanggod Street, Tannton
Someract TA1 1RY, England

FAX 011441823336824

Dear Brian:

We have tested the samples of the Dyneema material I gut from you when I was at Pearsalls. They have very good tensile strength but as you mentioned they are larger in diameter than the size 2 subtre we presently use. We do need for our test record more info on the 4 samples. If you could give me some basic specifications for our records I would appreciate it.

Can you build a 25% Dyneems / 75% polyester bland in a size 2 that is very flexible (like the existing subure or the ethicon sample) and send it to me to test? If we can get this blend correct, we will have a terrific advancement in subure for our soft tissue anchors.

Thank you

Don Grafton
V. P. Binginocring
Arthrex Inc.

DEPUY MITEK EXHIBIT 324 04cv12457

.

BROOKSTEIN DECLARATION EXHIBIT 7

TO:Arthrex

ATTN: Don Grafton

FROM: Brian Hallett

DATE: 16/11/98

SUBJECT: POLYESTER - DYNEEMA -(Braids)

Dear Don.

Please find enclosed a matrix of information of the samples that you took with you on your visit to Pearsalls, I will endeavour to proceed with the existing trial to match the US2 Excel Braid maid by Ethicon, in Polyester construction.

The next Poly/Dyneema sample should be with you by the end of the week

Yam Dyneema Poly/Dyneema Poly/Dyneema Poly/Dyneema	PA14	Runnage Mt/ Kg 3034 2984 3331	St/pull KG 23.12 36.27 34.95	Diameter MM 0.714 0.702 0.639	Extention % 24.39 18.33 18.83	PPI 46 48 48
Poly/Dyneema	PA14 Stretch	3469	36.41	0.628	14.32	48 48

Kind regards

Brian Hallett Product Development Manager



BROOKSTEIN DECLARATION EXHIBIT 8

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1
  1
                 IN THE UNITED STATES DISTRICT COURT
                  FOR THE DISTRICT OF MASSACHUSETTS
  2
  3
     DePuy Mitek, Inc., a
     Massachusetts Corporation,
  4
         Plaintiff,
  5
         vs.
                                        CIVIL ACTION
  6
                                        NO. 04-12457 PBS
     Arthrex, Inc., a Delaware
  7
     Corporation,
  8
         Defendant.
 9
10
    DEPOSITION OF:
                              PETER DREYFUSS
11
    DATE:
                              September 16,
12
    TIME:
                              8:59 a.m. ko
13
    LOCATION:
                              The Ritz 🕰
                                            ton Golf Resort
14
                              2600 Tiburan Drive
                                           34112
15
    TAKEN BY:
16
    REPORTER:
                                 orah A. Krotz, RPR, CRR
17
    VIDEOGRAPHER:
                              Les Smoak, CLVS
18
19
20
21
22
23
24
25
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I do on sutures.

- Q. But Arthrex doesn't specifically test for how3 much coating has been applied on FiberWire sutures from4 Pearsalls?
- 5 A. No, not that I'm aware of.
- 6 Q. Has Arthrex ever rejected a batch of bulk sutures 7 based on the amount of coating that's been applied to any 8 FiberWire sutures?
- 9 A. Not that I know of.
- 10 Q. Okay. And then Okay. Now back to ARM 8784 in 11 Exhibit 102, we've stretched and coated the suture or the 12 braid, and what's the next step?
- 13 A. It looks -- final inspection and measuring, which 14 would be QC.
- 15 Q. And how is that final inspection QC performed?
- 16 A. There's, as I understand, there's various steps.
- 17 Mechanical measuring, and there's a -- whatever -- by 18 feel, measuring for any imperfections.
- 19 Q. Popping maybe? Are you familiar with that term?
- 20 A. Not exactly.
- 21 Q. Okay.
- A. Just making sure the suture is homogenous,23 consistent, and strong.
- 24 Q. Now you said mechanical measuring. What kind of 25 mechanical measuring is used in the inspection process for

- 1 it related to the 16-carrier bobbin applies to Arthrex's 2 FiberWire No. 2 as sold in AR-7201; right?
- 3 A. Correct.
- 4 MR. FALKE: Why don't we break for lunch.
- 5 MR. TAMBURO: Sounds good.
- 6 VIDEOGRAPHER: Going off the record. We're off
- 7 (A lunch break was held from 11:47 a.m. to 12:47 8 p.m.)
- 9 VIDEOGRAPHER: Back on the record. 10 BY MR. FALKE:
- 11 Q. Okay, Mr. Dreyfuss, do you want to look at 12 Exhibit 120 for a minute. The coating that's shown in 13 Exhibit 120 and the bath of the coating, is that bath 14 comprised of 100 percent MED-2174?
- 15 MR. TAMBURO: Object to the form.
- 16 A. I believe it is, yes.
- 17 Q. Okay. So there's no solvent or any other 18 material used possibly to dissolve the coating?
- 19 A. I'm not aware of it, no.
- Q. Okay. But you understand the coating the bath
 of MED-2174 as used in the coating process for Arthrex's
 FiberWire sutures to be 100 percent MED-2174?
- 23 A. I believe so.

95

Q. Also, if we could go back -- That's okay. I'd25 like you to take that sheet of paper there in front of

1 Arthrex's FiberWire sutures?

- 2 A. There's a -- they actually measure the diameter 3 per a certain procedure or a certain approved protocol 4 that you measure the diameter at several places, several 5 locations along a certain piece of suture to get an 6 average diameter.
- Q. Does Arthrex provide specifications to Pearsalls8 for the inspection process of its FiberWire sutures?
- A. Yes.
- 10 Q. And what specifications are those?
- 11 A. Drawing on the drawing specifications, I would 12 assume.
- 13 Q. Okay.
- 14 A. And possibly in an inspection procedure that we15 have written up in a document form.
- 16 Q. Okay. And once the braid or the bulk suture has 17 been inspected and measured, what happens next?
- 18 A. If approved, I would assume it would be either —
 19 well, if it's part of an order, I would assume it's then
 20 be shipped to the customer, which would be ...
- 21 Q. And then that customer Strike that.
- The braiding process that we've talked about with 23 respect Strike that.
- The manufacturing process that we've talked about 25 with respect to ARM 8784 in Exhibit 102, that testimony as

- 1 you, and if you could, could you draw a cross-section of 2 Arthrex's No. 2 FiberWire?
 - A. I can I can try, yes.
- 4 Q. And list, please -- you know -- the various 5 materials and what not. And I'm going to mark your 6 drawing of a cross-section of Arthrex's No. 2 FiberWire 7 with Exhibit No. 121.
- 8 (DePuy Mitek Exhibit No. 121, drawing of Peter
- 9 Dreyfuss of the Approximate Cross-Section of Arthrey
- 10 2-0 FiberWire, was marked for identification.)
- 11 A. I luckily got eight. Oh. I approximated the 12 numbers.
- 13 Q. Okay. Did you say you drew eight?
- 14 A. I drew an eight -- a version of an eight-carrier 15 braid.
- 16 Q. Okay. And that would be a cross-section then of 17 Arthrex's 2-0 FiberWire suture?
- 18 A. Yes.
- 19 Q. Okay. So we're going to remark Exhibit 121 as a 20 drawing of Arthrex's 2-0 FiberWire suture; is that 21 correct?
- 22 A. Yes.
- Q. Okay. And if you could just label that and24 initial and date it, please.
- 25 A. (Witness complying).

25 (Pages 94 to 97)

- 1 Q. And I don't know if you did, but could you please 2 label the core and the cover?
- 3 A. Yes, I did.
- 4 Q. Okay.
- 5 A. I was doing a core with three parts to represent 6 the No. 2 suture. But since it's an 0, I'm not exactly 7 sure how many yarns are made up of the core, but they're 8 all UHMWP --
- 9 Q. Okay.
- 10 A. -- if that's acceptable.
- 11 Q. Okay. Yeah. Let me just take a look at it, 12 please.
- Okay. So but other than the core, which you're
 14 not quite sure of how many yarns make up the core on the
 15 2-0, this outside accurately represents the cover or the
 16 sheath of the Arthrex 2-0 FiberWire?
- 17 A. Yes.
- 18 Q. Okay. And as you have shown, going around the 19 cover or the sheath, the materials alternate PET, ultra 20 high molecular weight polyethylene, PET, ultra high 21 molecular weight polyethylene, et cetera?
- 22 A. Yes.
- 23 Q. Okay. Now within the sheath or the cover -- 24 Well, first could you just label the sheath and the cover 25 for me?

- 1 time? Ever since Arthrex is manufacturing a 2-0
- 2 FiberWire, it's been using this configuration as shown in 3 121?

101

- 4 A. Yes.
- 5 Q. Okay.
- A. (Witness complying).
- Q. And I'm going to mark your drawing of Arthrex's8 No. 2 FiberWire suture as DePuy Mitek Exhibit 122.
- 9 (DePuy Mitek Exhibit No. 122, drawing of Peter
- 10 Dreyfuss of the Approximate Cross-Section of No. 2
- 11 FiberWire, was marked for identification.)
- 12 Q. Can I take a look at it, please?
- 13 A. Yes.
- 14 Q. Okay. And so this shows a core made up of three 15 ultra high molecular weight polyethylene yarns twisted 16 together and then a cover or sheath composed of 17 alternating yarns of ultra high molecular weight 18 polyethylene and PET; is that right?
- 19 A. Correct.
- 20 Q. And the PET and ultra high molecular weight
 21 polyethylene that make up the sheath or cover of Arthrex's
 22 FiberWire No. 2 are in direct contact with each other; is
 23 that right?
- 24 A. Yes.
- Q. Okay. And they're intertwined around each other;

- 1 A. (Witness complying).
- Q. Are the individual yarns in the cover or sheath
- 3 of the Arthrex 2-0 FiberWire as shown in 121 in contact
- 4 with each other, meaning is the ultra high molecular
- 5 weight polyethylene yarn connected to the neighboring PET 6 yarn?
- 7 MR. TAMBURO: Object to the form.
- 8 A. They're all interdigitated. I'm sure there's
- 9 contact between them.
- 10 Q. Intertwined?11 A. Yes.
- 12 Q. Okay. So there is contact then between the
- 13 neighboring or adjacent PET and ultra high molecular 14 weight --
- 15 A. Yes.
- 16 Q. -- polyethylene yarns and the sheath or cover?
- 17 A. Yes
- 18 Q. Okay. Next, if you could, could you please draw
- 19 a cross-section of Arthrex's No. 2 FiberWire?
- 20 And -- I'm sorry. But before we go on, does
- 21 Exhibit 121 reflect the construction or the structure of 22 the 2-0 FiberWire as it's always been?
- 23 A. To the best of my knowledge, yes.
- Q. Okay. So the construction with the structure as
- 25 shown in 121 of a 2-0 FiberWire suture hasn't changed over

1 right?

- A. They're braided.
- 3 Q. Okay. Is that intertwining or --
- 4 A. Yes, they're ...
- 5 Q. Okay. And does Exhibit 122 accurately reflect 6 the construction of Arthrex's FiberWire No. 2 currently
- 7 and since its release or since it was first sold by
- 8 Arthrex?
- 9 MR. TAMBURO: Object to the form.
- 10 A. I believe so.
- 11 Q. Okay. Could you mark or title Exhibit 122?
- 2 A. (Witness complying).
- 3 Q. And next I was going to ask you to draw a
- 14 cross-section of the No. 5 Arthrex FiberWire suture, which
- 15 I believe is the same as Exhibit 122 that you have just
- 16 drawn with the exception of possibly the number of yarns
- 17 that comprise the core; is that right?
- 18 A. I believe that would be correct.
- 19 Q. Okay. And -- but the outside of the cover or 20 sheath of the Arthrex FiberWire No. 2 is the same as the
- 21 cover or sheath of the Arthrex FiberWire No. 2; right?
- 22 A. In the manner of braiding, yes.
- 23 Q. Right.
- 24 MR. TAMBURO: Object to the form.
- 25 Q. In the manner as you have shown in Exhibit

1 No. 122?

A. Yes.

- 3 Q. I misspoke there, but the outside or the cover of 4 the Arthrex FiberWire No. 5 is the same as the cover or 5 sheath of the Arthrex FiberWire No. 2; is that correct?
- A. That's correct.
- Q. Okay. The same in terms of configuration and 8 contact and intertwining; right?
- A. Yes.
- 10 Q. Okay. Next, if I can ask you to draw the 11 cross-section of Arthrex's No. 0 FiberWire.
- 12 A. Let's see.
- 13 Q. And I believe you testified earlier, and correct 14 me if I'm wrong --
- 15 A. Twelve.
- 16 Q. -- that there's twelve carriers?
- 17 A. Correct.
- 18 Q. Okay. And I also believe you testified earlier 20 core in Arthrex's Size 0 FiberWire; is that right?
- 21 A. That's correct.
- 22 Q. Okay.
- 23 A. I'm sorry; would you give me the number again?
- 24 MR. TAMBURO: Here.
- 25 A. All right.

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- Q. Now I'm going to mark your drawing of a 2 cross-section of Arthrex's No. 0 FiberWire with DePuy 3 Mitek Exhibit 123.
- (DePuy Mitek Exhibit No. 123, drawing of Peter
- Dreyfuss of the Approximate Cross-Section of Size 0
- FiberWire, was marked for identification.)
- Q. And I believe what you've drawn in Exhibit 123 is 8 that the cover or sheath of the Arthrex No. 0 FiberWire 9 has alternating yarns of PET and ultra high molecular 10 weight polyethylene; is that right?
- A. Correct.
- Q. And that -- and that those neighboring yarns in 13 the sheath or cover are in contact with each other?
- 14 A. Correct.
- 15 Q. And in the same configuration and intertwining 16 manner as Exhibits 122 and 121?
- 17 A. Correct.
- 18 Q. Okay. Could you draw for me a cross-section of 19 Arthrex's FiberWire 3-0 suture? I believe you testified 20 earlier that it's eight carriers.
- A. Thank you.
- 23 of Arthrex's FiberWire No. 3 suture with DePuy Mitek 24 Exhibit 124.
- (DePuy Mitek Exhibit No. 124, drawing of Peter 25

102

- 104 Dreyfuss of the Approximate Cross-Section of Size 3-0
- 2 FiberWire, was marked for identification.)
- Q. And just so the record's clear, all these hand
- 4 drawings that you have done so far, when it says UHMW 5 that means ultra high molecular weight polyethylene?
- A. Correct.
- Q. Okay. And what you've shown is that Arthrex's 8 No. 3-0 FiberWire has alternating yarns of PET and ultra 9 high molecular weight polyethylene?
- 10 A. Correct.
- 11 Q. And that those neighboring yarns and the sheath 12 or cover contact each other?
- A. Correct.
- 14 Q. And they're in the same -- you know --15 intertwining manner as Exhibits 123, 122, and 121?
- A. Correct.
- 17 Q. And now if you could just draw for me a

18 cross-sectional drawing of Arthrex's 4-0 FiberWire suture 19 that you weren't sure about how many yarns make up the 19 please. And I'm going to mark your drawing of Arthrex'

204-0 FiberWire suture with DePuy Mitek Exhibit 125.

- A. (Witness complying).
- 22 (DePuy Mitek Exhibit No. 125, drawing of Peter
- 23 Dreyfuss of the Approximate Cross-Section of Size 4-
- FiberWire, was marked for identification.) 24
- 25 Q. And I believe what you've shown in Exhibit 125 is

- 1 that, one, there's no core in the 4-0 FiberWire; right?
 - A. Correct.
- Q. And that the sheath or cover is made up of
- 4 intertwining yarns of ultra high molecular weight
- 5 polyethylene and PET?
- A. Correct.
- 7 Q. And that the neighboring yarns within the cover 8 or sheath are in contact with each other?
- A. Correct.
- 10 Q. Okay. Do Exhibits 123, 124, and 125 show not 11 only the present-day but the configuration of the
- 12 FiberWire sutures as sold in the past?
- A. Yes, to the best of my knowledge and --
- 14 Q. In other words, there hasn't been any different 15 configurations of Arthrex's 0, 3-0, and 4-0 FiberWire 16 sutures?
- 17 A. I'm not for certain on the 4-0.
- Q. Okay. But for the 2-0 and the -- or for the 0 19 and the 3-0 you are?
- 20 A. Yes.
- Q. Okay. And I don't think I asked you this, but in Q. And I'm going to label your cross-section drawing 22 Exhibit 125, the alternating sheaths -- alternating yarns 23 and the sheath or cover are in intertwining contact like 24 Exhibits 124, 123, 122, and 121?
 - 25 A. Yes.

- 1 Q. Okay. Now what I'd like you to draw is a 2 cross-section of Arthrex's TigerWire suture.
- 3 A. Okay. Which size? Actually, there's --
- 4 Q. That's a good question. How many sizes of 5 TigerWire are there?
- 6 A. No, technically, there's only one.
- 7 Q. Okay. Is that a No. 2 size?
- 8 A. Correct.
- 9 Q. Okay. So just to rephrase, can you please draw a 10 No. 2 TigerWire as sold by Arthrex?
- 11 A. (Witness complying).
- 12 Q. And I'm going to mark your drawing of No. 213 TigerWire as sold by Arthrex with DePuy Mitek Exhibit 126
- 14 (DePuy Mitek Exhibit No. 126, drawing of Peter
- 15 Dreyfuss of the Approximate Cross-Section of Size 2
- 16 TigerWire, was marked for identification.)
- 17 Q. Do you know how many carriers are in the Arthrex 18 No. 2 TigerWire?
- 19 A. Sixteen,
- Q. Sixteen. So the configuration of the sheath or 21 cover in Arthrex's No. 2 TigerWire is exactly the same as 22 the sheath or cover as Arthrex's No. 2 FiberWire with the 23 exception that one of the PET carriers has been replaced 24 with a black nylon-carrier?
- 25 A. Correct.

- 1 A. Not to my knowledge, no. Not ...
- 2 Q. If you could turn to Page ARM 9003. Now you can

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- 3 I'm sorry; it's the page before also, ARM 9002.
- I'm going to ask the question again. If you need to reference this page, go right ahead. Can you explain to me the process that Pearsalls goes through to manufacture Arthrex's FiberTape?
- 8 A. In short, a tape component is They use the 9 a braiding machine? But the carriers are configured in 10 such a way that the braids don't the ends of the 11 carriers don't actually cross, and, therefore, it's an 12 open braid which, when it's taken up on the takeup spool 13 it flattens out, makes a tape. That tape is then 14 incorporated stitched into a piece of FiberWire suture 15 along its length with a length of the length of 16 FiberWires on the ends which have no tape. The middle 17 portion of the construct is FiberWire and FiberTape 18 interstitched, and the ends and the FiberTape ends within 19 the FiberWire, and then there's ends of FiberWire outside 20 of that.
- 21 Q. Okay. So does Arthrex's FiberTape include an 22 Arthrex No. 2 FiberWire suture?
- 23 A. Yes.
- Q. And does it include the Arthrex FiberWire No. 225 suture as depicted in Exhibit 122?
- 1 Q. Okay. So the sheath has alternating yarns made 2 up of ultra high molecular weight and polyester or PET 3 with the exception of one carrier that is black nylon?
- A. Correct.
- 5 Q. Okay. And the adjacent yarns in the sheath are 6 in contact with each other in the same intertwining manner 6 7 as Exhibits 125, 124, 123, 122, and 121?
- 8 A. Correct.
- 9 Q. Okay. All right. Thank you.
- Okay. Now I'd like to talk about FiberTape.

 11 Could you explain to me the process that Pearsalls goes
 12 through to manufacture FiberTape from the stage of
 13 individual yarns?
- 14 Actually Do you know what? I might have a 15 document here that would help you out.
- 16 I'm going to show you what's being marked as 17 DePuy Mitek Exhibit 127. It's a document with Bates 18 numbers ARM 8847 through 9091.
- One is double-sided; one isn't. That one goes to 20 Sal. No. I'm sorry. That one goes to Sal.
- 21 Okay. We're talking about Exhibit No. 127.
- 22 (DePuy Mitek Exhibit No. 127, Technical File
- 23 Arthrex FiberWire Volume 2, was marked for
- 24 identification.)
- Q. Have you seen Exhibit 127 before?

- 1 A. Yes.
- 2 Q. Can you just draw for me, please, the 3 cross-section of an Arthrex FiberWire Tape as --
- 4 A. Can I -- May I simplify it? Representative of 5 FiberWire and tape without all ...
- 6 Q. Sure. You can start about that, and if I'm 7 confused or need more, then I'll let you know. But you 8 can start with that.
- 9 MR. TAMBURO: I'm going to object to this line of questioning regarding FiberTape as outside the scope of the notice, which seems to be limited to FiberWire sutures.
- 13 MR. FALKE: Well ... I think we defined in our
- 14 first set of either documentary requests or
- 15 Interrogatories as FiberWire including FiberWire or
- any product that includes FiberWire, but your
- objection is -- you know -- it's your objection.
 MR. TAMBURO: I thought I heard a different control of the control
- MR. TAMBURO: I thought I heard a different definition today of FiberWire suture that would not include FiberWire Tape.
- MR. FALKE: Right. But I think the notice was probably using the definitions of the other discovery, not necessarily definitions of mine, but --
- 24 MR. TAMBURO: Fine. I just wanted to note my 25 objection.

- Q. What is FiberStick, sold under AR-7209?
- A. FiberStick is a length of FiberWire that has a -
- 3 a long length of it that is tipped or stiffened with the
- 4 Loc-Tite, and it makes it easier to perform certain 5 actions with.
- Q. Other than the difference in the length of
- 7 stiffening on the end of FiberStick, is there any other
- 8 difference in any way between FiberStick AR-7209 and the
- 9 blue FiberWire in AR-7201?
- 10 A. Just the overall length is longer.
- 11 Q. Okay. So is the structure and configuration in 12 FiberStick AR-7209 the same as the No. 2 FiberWire in
- 13 Exhibit 122?
- 14 MR. TAMBURO: Object to form.
- 15 A. Yes.
- Q. Does the No. 2 FiberSnare in AR-7209SN have the 17 same structure and configuration as the No. 2 FiberWire in 18 Exhibit 122?
- 19 MR. TAMBURO: Same objection.
- 20 A. I believe so. I'm not for sure on this one 21 product.
- 22 Q. Okay. What's your understanding of what 23 FiberSnare is as sold under AR-7209SN?
- 24 A. No, I only understand I'm I'm familiar on 25 the surface with this product, and I've seen different

- 1 122 Exhibit 122?
- MR. TAMBURO: Object to form. And it
- mischaracterizes the exhibit.
- A. Yes.
- Q. Does the No. 5 FiberWire sold with AR-7219 have

124

125

- 6 the same structure and configuration as the suture shown 7 in Exhibit 122?
- MR. TAMBURO: Same objection.
- A. Yes.
- Q. Okay. Does the No. 5 TigerWire shown or sold
- 11 with AR-7219 have the same structure and configuration as 12 the No. 2 TigerWire in Exhibit 126?
- 13 MR. TAMBURO: Object to form.
- 14 A. Yes.
- 15 Q. And the No. 2 FiberWire sold under AR-7219, does
- 16 that have the same structure and configuration as the No. 172 FiberWire shown in Exhibit 122?
- 18 MR. TAMBURO: Same objection.
- 19 A. Sorry. Did you say FiberWire?
- Q. Yeah. Do you want me to repeat it?
- 21 A. Please.
- 22 Q. Okay. And the No. 2 FiberWire sold under
- 23 AR-7219, does that have the same structure and
- 24 configuration as the No. 2 FiberWire shown in Exhibit 122?
- 25 MR. TAMBURO: Same objection.
- I appearances of it, so I can't answer for sure. It doesn't
- 2 appear I've seen it in appearance it looked a little
- 3 different, so I don't want to answer --
- Q. Okay.
- 5 A. - incorrectly.
- Q. Okay. Does the No. 2 TigerStick of AR-7209T the
- 7 same -- have the same structure and configuration as the
- 8 No. 2 FiberWire in Exhibit 126?
- MR. TAMBURO: Object to form.
- 10 A. Yes.
- Q. Do you understand what I'm saying when I say
- 12 structure and configuration?
- 13 A. Yes, I interpret it as approximately the same 14 makeup.
- 15 Q. As that shown?
- A. As that shown.
- O. Okay. Does the No. 5 FiberWire AR-7210 have the 18 same structure -- Strike that.
- Does the No. 5 FiberWire in AR-7210 have the same 20 structure and configuration as the No. 5 FiberWire shown 21 in Exhibit 122?
- 22 MR. TAMBURO: Objection to form.
- 23 A. Yes.
- Q. And does the No. 5 FiberWire AR-7211 have the
- 25 same structure and configuration as the FiberWire shown in

1 A. Yes.

- 2 Q. And the No. 2 FiberWire sold under AR-7220 and
- 3 AR-7221, do they have the same structure and configuration 4 as the 2-0 suture shown in Exhibit 121?
- MR. TAMBURO: Object to form.
- A. Yes.
- Q. And the No. 2 -- excuse me. Does the 2-0
- 8 FiberStick have the same structure -- Strike that.
- Does the 2-0 FiberStick in AR-7222 have the same 10 structure and configuration as the 2-0 FiberWire shown in
- 11 Exhibit 121?
- 12 MR. TAMBURO: Same objection.
- 13 A. Yes.
- 14 Q. Does the 3-0 FiberWire in AR-7225 and AR-7227-01
- 15 and -02 have the same structure and configuration as the
- 163-0 FiberWire shown in Exhibit 124?
- 17 MR. TAMBURO: Same objection.
- 18 A. Yes.
- 19 Q. Does the 4-0 FiberWire sold under AR-7228,
- 20 7230-01, and 7230-02 have the same structure and
- 21 configuration as the 4-0 FiberWire suture in Exhibit 125?
- 22 MR. TAMBURO: Same objection.
- 23 A. Yes.
- Q. Does the 4-0 FiberLoop in AR-7229-12 and
- 25 AR-7229-20 have the same structure and configuration as

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                 IN THE UNITED STATES DISTRICT COURT
                   FOR THE DISTRICT OF MASSACHUSETTS
  2
  3
     DePuy Mitek, Inc., a
     Massachusetts Corporation,
  4
          Plaintiff,
  5
          vs.
                                         CIVIL ACTION
  6
                                         NO. 04-12457 PBS
     Arthrex, Inc., a Delaware
  7
     Corporation,
  8
         Defendant.
  9
 10
     CONTINUATION
 11
     DEPOSITION OF:
                          PETER DREYFUSS
12
     DATE:
                          December 7, 2005
13
    TIME:
                          8:03 a.m. to 1:2
14
    LOCATION:
                          The Staybridg
                          4805 Tamiami
                                         Trail North
15
                          Naples
16
    TAKEN BY:
17
    REPORTER:
                               ah A. Krotz, RPR, CRR
18
    VIDEOGRAPHER:
                          Michael Sturdevant, CLVS
19
20
21
22
23
24
25
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- 1 Q. And if you see in the second paragraph, second
 2 sentence, it says, "The Black/White Suture commonly knows
 3 as TigerWire has a blend of nylon and the ultra high
 4 molecular weight polyethylene." Do you see that?
- 5 A. Yes.
- 6 Q. And if you skip a sentence, it says, "In place of 7 the nylon, a silk suture will be used." Do you see that?
- 8 A. Yes, I do.
- 9 Q. Is the only difference between Arthrex's 10 TigerWire and Arthrex's FiberWire with silk is the silk 11 suture is used in place of the nylon marker strand in 12 Arthrex's TigerWire product; is that right?
- 13 MR. SABER: Object; vague and confusing question.
- 14 Q. Do you understand the question?
- 15 A. I understand, I believe, from what I read here 16 that that is true.
- 17 Q. And the last time we were here, you described the 18 design and construction of the TigerWire product. Do you 19 remember that?
- 20 A. Yes, I understand that.
- 21 Q. What is the purpose of the nylon marking strand 22 in Arthrex's TigerWire product?
- 23 A. Identification. Visual identification.
- Q. Is there any other purpose to the nylon marking 25 strand in Arthrex's TigerWire product?

- 1 Q. But they show But a No. 2 TigerWire, for
- 2 instance, and a No. 2 FiberWire show very similar knot 3 strength, tensile strength, handleability, and what not,

77

- 4 all of the characteristics that define FiberWire?
- A. I believe so.
- 6 Q. Okay. And is that true also with the
- 7 introduction of silk rather than a nylon marker?

 8 A. I don't know.
- 9 Q. Do you know whether the silk used in the 10 FiberWire with silk suture affects any of the
- 11 characteristics of the suture?
- 12 A. No, I don't.
- 13 Q. Based on your understanding of Arthrex's 14 FiberWire with silk product, do you think you would be 15 able to draw a cross-section of the suture?
- 16 A. I No.
- 17 Q. No? But as far as you know, the only difference18 between the TigerWire and a FiberWire with silk is instead19 of the nylon, it's a piece of silk?
- 20 A. That would be a good generalization.
- 21 Q. Okay. And Don Grafton would know this 22 information?
- 23 A. I believe so, yes.
- 24 (DePuy Mitek Exhibit No. 142, Design History File
- 25 for FiberWire 3-0 and 4-0, ARM 6580 through 6950, was
- 1 A. That's the primary purpose. I'm not sure if 2 there's secondary purposes, per se.
- Q. Does the introduction of a nylon marking strand4 in the TigerWire product affect any of the physical
- 5 characteristics of the TigerWire product?
- 6 A. Affect in --
- 7. Q. Other than the visual distinction that you can
- 8 see with the introduction of a nylon marking strand, does
- 9 the nylon marking strand in TigerWire affect any other 10 characteristic of the braided suture?
- To characteristic of the braided
- 11 A. Yes.
- 12 Q. What is -- what?
- 13 A. Minute differences in its feel and strength, 14 characteristics.
- 15 Q. But you would describe them as minute 16 differences?
- 17 A. Not enough to cause it not to become a product.
- 18 Q. Can you explain that?
- 19 A. It's --
- 20 Q. In other words, the introduction of the nylon
- 21 marking strand doesn't affect any of the marketing
- 22 qualities or engineering qualities that make FiberWire
- 23 FiberWire; does that make sense?
- 24 MR. SABER: Objection; vague.
- 25 A. It -- They are comparable.

- 1 marked for identification.)
- Q. I'm going to hand you a document labeled DePuy
- 3 Mitek Exhibit 142. It's a document with Bates numbers ARM 4 6580 through 6950.
- 5 Have you seen Exhibit 142 before?
- 6 A. I believe so.

- 7 Q. And what is DePuy Mitek Exhibit 142?
- 8 A. The Design History File for FiberWire new sizes
- 9 new sizes of FiberWire.
- 10 Q. And what new sizes for FiberWire?
- 11 A. 3-0 and 4-0.
- 12 Q. Do you have any reason to believe the information
- 13 in Exhibit 142 is inaccurate?
- 14 MR. SABER: Objection; overbroad.
- 15 A. No, I don't.
- 16 MR. FALKE: I'm just trying to authenticate the
- 17 document.
- 18 MR. SABER: No, I have no problem with you
- 19 authenticating the document, but I you know this
- 20 is, again, a document of hundreds of pages. And to
- 21 ask him to a generalized question like that I think
- 22 is kind of unfair.
- 23 BY MR. FALKE:
- Q. Do the instructions for use that are included25 with all of Arthrex's FiberWire product indicate that the

BROOKSTEIN DECLARATION EXHIBIT 9

DEC.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Alastair W. Hunter, et al.

Serial No.:

838,511

Art Unit:

1504

Filed

February 19, 1992

Examiner:

C. Raimund

For

STERILIZED HETEROGENBOUS BRAIDS

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Natthey S. Goodwin

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6443.W 1500

December 2, 1992

(Date of Signature)

Hon. Commissioner of Patents and Trademarks Washington, D.C. 20231

AMENDMENT

Dear Sir:

Please reconsider the above-identified application in view of the following remarks. These remarks are subdivided into a discussion of the claimed invention, and an analysis of the rejection, to facilitate an understanding of the significant differences between the cited art and the claimed invention.

Discussion of the Invention

A proper understanding of the invention is critical for appreciating the dissimilarities between the invention and the teachings of the cited references.

In a broad sense, the invention is a braided suture which contains dissimilar filaments of first and second fiber-forming materials. However, the proper characterization of the claimed suture goes far beyond this simple description.

DePuy Mitek, Inc. v. Arthrex, Inc. C.A. No.04-12457 PBS

DMI000618

The braided suture is made up of multifilament varns. A multifilament yarn is a bundle of individual filaments which are integrated to form a single unit, that is, an individual multifilament yarn. The braided suture has a first and second set of these multifilament yarns in a braided construction. Each of the filaments of the first set of yarns is composed of a first fiber-forming material. Similarly, each of the filaments of the second set of yarns is composed of a second fiber-forming material.

The importance of the construction of the first and second set of yarns cannot be diminished. The braided construction is not accurately characterized by simply referring to a suture with filaments of dissimilar fiber-forming materials in a braided construction. Rather, filaments of a first fiber-forming material must be <u>bundled</u> to prepare a first set of multifilament yarns, and filaments of the second fiber-forming material must also be bundled to prepared the second set of multifilament yarns.

Once an understanding of the composition and construction of each set of first and second yarns is achieved, the importance of a further characterization of the braid construction can now be understood and appreciated. One yarn from the first set of yarns is in direct intertwining contact with a yarn from the second set of yarns. This limitation does not simply mean that the dissimilar filaments are fabricated into a braided construction, that is, dissimilar filaments are in "intertwining contact". Rather it is a multifilament yarn which is in direct intertwining contact with another multifilament yarn. Again, it is important to emphasize here that the multifilament yarns are integrated bundles of individual filaments, and it is this integrated bundle of filaments of a first fiber-forming material which is in direct intertwining

contact with another integrated bundle of individual filaments of a second fiber-forming material.

One way to accurately characterize the braided suture of this invention is to refer to it as a <u>structured</u> mechanical blend of dissimilar fiber-forming materials. The fiber-forming materials are first arranged into integrated bundles to form multifilament yarns and then these multifilaments yarns are further arranged so that at least one yarn from the first set of yarns directly intertwines with a multifilament yarn from the second set of yarns. This can be contrasted with a <u>random</u>, braided construction where filaments of dissimilar fiber-forming materials are randomly braided with one another to form a braided suture.

The heterogeneous braids of this invention exhibit truly outstanding and surprising properties. The integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual multifilament yarns (see the specification at page 4, lines 30-33). In the preferred embodiment, each yarn from the first set of multifilament yarns is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar multifilament yarns (see the specification at page 6, lines 28-31, and claim 15). In this way, yarn compatibility can be further enhanced and the overall physical and biological properties of the heterogeneous braid can be further improved as well.

What is truly surprising with respect to the claimed heterogeneous braid construction is that certain bulk properties of the claimed braid are better than what one skilled in the art would expect. A skilled artisan would expect the properties of the braid to simply follow the "Rule of Mixtures", where the bulk property

measured would be estimated to be a weighted average of its component properties. Upon studying the Examples in the specification, it will be noted that the bending rigidity of the heterogeneous braids in Examples 1 and 2 do not follow the Rule of Mixtures, but surprisingly show an enhanced bending rigidity relative to the weighted average of their filament components. This behavior is not achieved when dissimilar individual filaments are randomly braided to form the braided suture.

In setting forth the claimed invention, the heterogeneous braid does not encompass braided sutures with randomly braided individual filaments, as described in detail above. Further, the claimed heterogeneous braid could not be construed to cover known braids which have a core of longitudinally extending yarns composed of filaments of a first fiber-forming material, and a sheath of braided yarns composed of a second set of filaments of a dissimilar fiber-forming material. This braid construction does not fall within the scope of the claimed braid because these sheath yarns are not in direct intertwining contact with any of the core yarns. In other words, none of the sheath yarns are braided about a core yarn, but simply shroud the core yarns to form the sheath construction.

Analysis of the Rejection

1. Claims 21 and 23 were rejected under 35 USC §102(b) as being clearly anticipated by Doddi et al. ("Doddi"). Doddi does not anticipate the claimed suture, and therefore this rejection should be withdrawn.

The Examiner has correctly pointed out that Doddi does indeed disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47~56).

However, as discussed in detail above, more is required to meet the limitations of the claimed suture than just a disclosure concerning filaments of two different polymers in a braided configuration. Doddi teaches nothing more than braiding individual filaments, and fails to provide any guidance as to how that braiding should be carried out. Therefore, one skilled in the art would be lead to believe that what Doddi had in mind was to simply braid individual filaments in a randomized fashion to fabricate a multifilament suture. It is important enough, however, to reemphasize again that the claimed braid requires the bundling of individual filaments into an integrated unit to form a multifilament yarn. It is this multifilament yarn which directly intertwines with another multifilament yarn to form Applicants' braid construction.

Since Doddi only teaches randomly braiding filaments of dissimilar fiber-forming materials, it does not anticipate the claimed braided suture. Doddi simply fails to enable one skilled in the art to construct a braided suture in the manner set forth by Applicants, and it is axiomatic that a reference which lacks enablement is deficient as a reference to anticipate a claimed invention. Accordingly, it is respectfully requested that the rejection of claims 21 and 23 under 35 USC §102(b) as being clearly anticipated by Doddi be withdrawn.

2. Claims 22 and 24 were rejected under 35 USC §103 as being unpatentable over Kaplan et al. ("Kaplan") taken with Doddi. The Examiner asserts it would have been obvious to substitute PET and PTFE fibers of Doddi for the filaments of Kaplan to arrive at Applicants' claimed suture. Applicants respectfully traverse this rejection for the reasons given below.

The Examiner correctly points out that Kaplan discloses a ligament prosthesis made from a core component and a braided sheath component as illustrated in Figures 3 and 4, and discussed at column 8, line 65, through column 9, line 34. However, Kaplan suffers from the same deficiencies as does Doddi, and therefore fails to teach or suggest the claimed braided suture.

Firstly, the Examiner has made specific reference to the Kaplan specification regarding the makeup of the core components and the sheath yarn component. The only component which has a braided construction is the sheath yarn component. It is clear from Figure 3 of Kaplan that none of the sheath yarn components are in direct intertwining contact with the core component. In other words, the sheath yarn component is a true "sheath" which shrouds the core but is not in any way integrally braided with the core. Therefore, since the core is not in a braided construction, its composition is irrelevant with respect to the claimed braided suture.

When the focus is shifted to the more relevant aspect of the Kaplan disclosure, specifically the sheath yarn component, the Examiner has correctly pointed out that the sheath yarn component may be "fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being non-absorbable". (Column 9, lines 25-28). However, Kaplan neither teaches nor suggests how his sheath yarn component is to be fabricated from these dissimilar individual filaments, nor is there any guidance to one skilled in the art as to how such dissimilar individual filaments are to be braided. Accordingly, just as was the case with the deficient Doddi reference, one skilled in the art could only be lead to randomly braid the dissimilar individual filaments into a braid construction.

The teaching of Kaplan once again lacks the <u>essence</u> of the claimed invention, which is: bundled filaments of a first fiber-forming material form a first set of a multifilament yarns, and at least one of these multifilament yarns is intertwined with a multifilament yarn composed of bundled filaments of a second fiber-forming material. To put it bluntly, Kaplan teaches <u>randomized</u> braiding, and the claimed suture sets forth a structured braid. This difference is not trivial, as pointed out with reference to the discussion of Applicant's specification, and particularly Examples 1 and 2.

It should also be pointed out here that even if Doddi and Kaplan were combined, their combined teachings would still fail to meet the limitations of the claimed braided suture. This is so because neither reference, taken singularly or in combination, discloses a <u>structured</u> braid set forth in the claims, but merely sets forth randomized braiding of individual filaments.

For all of the reasons given above, especially taken in light of the detailed discussion of the claimed braided suture and its surprising advantages, the rejection of claims 22 and 24 under 35 USC §103 as being unpatentable over Kaplan taken with Doddi is improper. Accordingly, it is respectfully requested that this rejection be withdrawn.

3. Applicants acknowledge with gratitude the withdrawal of the rejection of claims 21-24 under 35 USC §103 as being unpatentable over Burgess, expressed in the previous Office Action dated July 8, 1992. (Paper No. 3). It is presumed that Applicants' response to this rejection in their Amendment dated August 6, 1992, spelling out the distinctions between Burgess and the claimed

invention, clearly convinced the Examiner that the claimed surgical suture is patentable over this art.

- 4. The prior art made of record and not relied upon by the Examiner is duly noted, and does not affect the patentability of Applicants' claimed invention.
- 5. Since all formal requirements appear to have been met, and the claimed invention is patentable over the art of record or any other art of which Applicants are aware, Applicants respectfully solicit a Notice of Allowance at the Examiner's earliest convenience.

Respectfully submitted,

Matthew S. Goodwin Attorney for Applicant Reg. No. 32,839

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (908) 524-2794 December 2, 1992

BROOKSTEIN DECLARATION EXHIBIT 10

Marks' Standard Handbook for Mechanical Engineers

Revised by a staff of specialists

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MARKS' STANDARD HANDBOOK FOR MECHANICAL ENGINEERS

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The editors and the publishers will be grateful to readers who notify them of any inaccuracy or important omission in this book

Kind	Source	Length of fiber, in.	Width or diam of cells, microns	Specific gravity	Mois- ture regain,‡ percent		Principal uses
Cotton	Plant seed hair	5/8-2	8-27	1,52	8.5	Cellulose	Industrial, household, apparel
Jute†	Plant bast	50-80	15-20	1.48	13.7	Lignocellu-	Bagging, twine, carpet backing
Wool	Animal	2–16	10-50	1.32	17	Protein	Apparel, household, industrial
Viscose	Manufac- tured	Any	8-43	1.52	11	Regenerated cellulose	Apparel, industrial, household
Cellulose acetate	Manufac- tured	Any	12-46	1.33	` 6	Cellulose ester	Apparel, industrial, household
Nylon	Manufac- tured	Any	8	1.14	4.2	Polyamide	Apparel, industrial, household
Casein	Manufac- tured	Any	11–28	1.3	4.1	Protein	Apparel
Flax†	Plant bast	12-36	15–17	1.5	12	Cellulose	Household, apparel, industrial
Hemp†	Plant bast		18-23	1.48	12	Cellulose	Twine, halyards, rig- ging
Sisal†		30–48	10-30			Lignocellu- lose	Twine, cordage
Manila†	Plant leaf	60140	10-30			Lignocellu-	Rope, twine, cordage
Ramie†		310	24-70	1.52		Cellulose	Household, apparel,
Silk	Silkworm	Any	5–23	1.35	11	Protein	Apparel, household, industrial
Glass	tured	Any	3	2.5	0	Fused metal .	Industrial, household
Dacron	Manufac-	Any	8	1,38	0.4	Polyester	Apparel, industrial,

.Table 2. Tensile Properties of Single Fibers*

Fiber	Breaking tenscity, gpd	Extension at break, percent	Elastic recovery at corresponding strain, percent	Elastic modulus,† gpd
Glass	6.0-7.3 6.0-7.0	3.0-4.0 6	100 at 2.9 100 at 1.2 60 at 2.4	200-300 150-200
Flax	2.6-7.7	2.7-3.3	65 at 2	
Nylon 6, 6	4.6-9.2	16-32	100 at 8	25-50
Nylon 6	4.5-8.6	16-40	100 at 8	2550
Silk	2.4-5.1	10-25	92 at 2	75-125
Saran	1.1-2.3	15-25	95 at 10	•
Cotton	3.0-4.9	3-7	74 at 2	50-100
Steel (90,000 pei T.S.)	0.9	28		300
Steel (music wire)	3.5	8		300
Viscose rayon:	1.5-5.0	15-30	82 at 2	50-150
Wool	1.0-1.7	25-35	99 at 2	25-40
Acetate rayon	1.3-1.5	23-34	100 at 1	25-40
Polyester	4.4-7.8	10-25	100 at 2	50-80
Polypropylene	4.0-7.0	15-25	95 at 7	15-50
Polytetrafluoroethylene	1.7	13		

^{*}From Kaswell, "Wellington Sears Handbook of Industrial Textiles," Wellington Sears Co., Inc. †From Kaswell, "Textile Fibers, Yarns, and Fabrics." Reinhold.

¹ in = 0.0254 m; 1μ = 10⁻⁶ m. The more up-to-date term for the micron (μ) is the micrometer (μm).

*Adapted from Smith, Textile Fibers, Proc. ASTM, 1944; Appel, A Survey of the Synthetic Fibers, Am. Dyesuff Reporter,
34, 1945, pp. 21-26; and other sources.

†These fibers are commercially used as bundles of cells. They vary greatly in width. Width figures given are for the individual cells.

‡In air at 70°F and 65 percent relative humidity.